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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,764	03/12/2002	John Andrew Chaddock	1581.0900000/RWE/MTT	2729

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,764

Applicant(s)

CHADDOCK ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-40 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 22-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Lack of Unity of Invention(s)

- 1) Claims 1-21 have been canceled.
New claims 22-40 have been added.
Claims 22-40 are pending and are under prosecution.
- 2) The instant inventions lack unity under PCT Rule 13.1 and 13.2:
 - I. Claims 22-30 and 37-40, drawn to a method of reducing toxicity of a clostridial toxin derivative preparation by contacting with a ligand; and a method of removing a clostridial toxin from a preparation containing the toxin and a derivative of the toxin using a first and a second ligand, classified in class 530, subclass 413
 - II. Claims 31 and 32, drawn to an affinity chromatography column comprising a ligand that selectively binds to toxin, but not to the toxin derivative, classified in class 436, subclass 535
 - III. Claims 33, drawn to a clostridial toxin derivative preparation comprising 1-100 ppm clostridial toxin per toxin derivative, classified in class 424, subclass 832
 - IV. Claims 34-36, drawn to a composition comprising a clostridial toxin derivative, a pharmaceutically acceptable carrier and a ligand that selectively binds to the toxin, classified in class 514, subclass 2
- 3) Groups I-IV are drawn to multiple inventions that lack unity of inventions. The special technical feature of the first claimed method is a method of reducing toxicity of a clostridial toxin derivative preparation by contacting with a ligand. The special technical feature of inventions II, III and IV are an affinity chromatography column comprising a ligand that selectively binds to toxin, but not to the toxin derivative; a clostridial toxin derivative preparation comprising 1-100 ppm clostridial toxin per toxin derivative; and a composition comprising a clostridial toxin derivative, a pharmaceutically acceptable carrier and a ligand that selectively binds to the toxin respectively. However, these special technical features do not define over the prior art, since the prior art already taught the method, the column and the preparation. For instance, Gimenez *et al.* (*J. Protein Chem.* 12: 351-363, 1993) taught a method of contacting a type A clostridial neurotoxin contained in a buffer and digested with pepsin (i.e., a clostridial toxin derivative preparation) with cationic DEAE-Sephadex or Mono Q in a column wherein the 42K fragments (i.e., toxin derivatives) did not bind to

DEAE-Sephadex or Mono Q, but the 147 kD toxin did bind (see sections 3.3 and 2.5; Figure 3; and paragraph bridging pages 358 and 359). Gimenez *et al.* taught the chromatographically purified clostridial neurotoxin fragments (i.e., derivatives) that were dialyzed, ammonium sulfate-precipitated, and further dialyzed to obtain purified fragments (see section 3.5). The chromatographic elution results depicted in Figure 5D shows that the toxin fragments were free of the 147 kD toxin. Therefore, inventions I, II, III and IV do not share significant reagents or compositions, and/or methods steps.

4) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (703) 872-9306.

5) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

September, 2004